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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,821	12/21/2000	Daniel C. Carter	P06896US00/BAS	6567

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/740,821	CARTER, DANIEL C.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 Demcember 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-27* is/are pending in the application.

4a) Of the above claim(s) *13,16 and 21-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12,14,15,17-20 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DTAILED ACTION

The response filed 18 December 2002 (Paper No. 8) as to cancellation of claims 4 and 5, addition of claims 21-27 and amendment of claims 1, 7, 9, 11-12 and 17 have been entered. Applicant's request for extension of time of three months filed 18 December 2002 (Paper No. 7) has been entered.

Newly submitted claims 21-26 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: each claim refers to the amino acid sequence with SEQ ID NOs:1-5 (claims 22-26) and without SEQ ID NO: (claim 21), respectively; since all the sequences have not been disclosed prior to the first Office action in the specification. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-26 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Therefore, the following pending claims 1-3, 6-12, 14-15, 17-20 and 27 are examined in this Office action.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification while being enabling for the cosmetic composition comprising human serum albumin (HAS) and preparing the composition thereof, does not reasonably provide enablement for the composition comprising any modified (mutated) HAS protein variants as set forth in claim 20 of the current application.

Claim 20 recites "a modified human serum albumin that has at least one mutation...". Such the claim language encompasses numerous mutants that are unpredictable both structurally and functionally.

Applicant is in possession of the composition comprising the naturally-occurring HAS and the defined engineered HAS proteins, e.g., those set forth in claims 21-26. Applicant is not in possession of the claimed composition comprising any HAS mutant(s). The specification provides insufficient guidance and no working examples in this regard.

The claims encompass many structural variants; none have been described in the specification nor in the claims. The specification of the application does not describe relationships between the structural variation at N-terminus of the albumin and cosmetological activity, and between the structural variation at N-terminus of the albumin and albumin's affinity for the binding region VI of the protein.

The current disclosure sets froth that mutation at N-terminal region so as to reduce or eliminate the HAS affinity for trace metal ions (see claim 20). Kragh-Hansen, U. et al. (*Biochem.*

J. (1994) 301, 217-223) shows that mutational modification of N-terminal amino acid residues of HAS produces varied results; some decrease the affinity for metal ions while some increase the affinity (e.g., 125% of the modified *versus* wild type HAS protein) (see abstract and Tables 1-2). In addition, even the same mutant has different affinity for metal ions, *e.g.*, Arg-albumin (additional Arginine attached to N-terminus of the albumin) has increased affinity compared to naturally-occurring HSA protein (see association constant values of Table 2, page 219). Given the lack of sufficient guidance and working examples, predicting what changes can be made to N-terminus of the albumin that after addition (to the terminus), insertion, substitution, and deletion will retain the desired folding structure or cosmetic activity is unpredictable. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and co. 43 USPQ2d 1398.*

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Response to the rejection under USC 35 112, the first paragraph

The response filed 18 December discusses the enablement issue as to the claims of the present application apart from claims 4 and 5, and asserts that the skilled artisan would readily be enabled by the specification to make and use the claimed (see the bridging page 3-4). The applicant's argument is not persuasive because of the reasons stated in the foregoing. Applicant states that the HAS protein can be isolated in natural form, or through recombinant means (see page 3, the second paragraph). Yet, the recombinant production of the albumin is subject to the

biological instability or proteolysis from N-terminal of HAS polypeptide (see the statement *supra*). Because the specification is silent in this regard, the disclosure needs to provide teaching and guidance of this for the enablement.

It should be stressed that make and use of the modified albumin (*i.e.*, recombinantly generated mutant albumin, see claim 20) is unpredictable with respect to the binding of trace metal ions which in turn affect quality of cosmetically useful product comprising the variant HSA proteins, for which the specification provides neither guidance nor working examples. The detailed rationale in this regard has been set forth *supra*.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 is indefinite in the recitation "other beneficial cosmetics or dermatological purpose ..."; what is the said beneficial purpose?

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims 1-3, 8, 9, 14-15, 17 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kligman, A. M. (EP 0244859).

Kligman teaches a composition comprising human serum albumin (see abstract and claims 1 and 5) which is in a form of a lotion (see page 3, lines 33-38), as applied to claims 1-3 and 27 of the current application.

Kligman teaches the composition comprising the HSA protein that is in glycerin solution (see the patent claim 8), as applied to the application claim 8.

Kligman teaches that the albumin is dissolved in an aqueous carrier, e.g., glycerin and final concentration of glycerin in the disclosed composition is 5% (see the patent claims 6-7 and claim 8 which discloses the said glycol is glycerin), and the composition comprises as much as 50% (by weight) of the human serum albumin, in order to achieve 5% glycerol concentration in the composition, the calculated glycerin for dissolution of the albumin would be 10%; thus, the Kligman teaching is also applied to claim 9 of the instant application.

Kligman teaches the composition comprising the HSA protein that is in glycerin solution (see the patent claim 8) of a concentration in the range of about 5-50% by weight (see the patent claim 4), and teaches HAS is dissolved in ~ 10% glycerin solution (see the above), which meet the limitation 0.1-6 g/100ml (*i.e.*, 1-60 mg/ml). Thus, the Kligman teaching is also applicable to the application claim 17.

Kligman teaches a method of preparing a skin treating composition comprising admixing HAS protein with aqueous carrier (e.g., glycerine) and cosmetic agent (e.g., titanium dioxide or

sodium silicate [see abstract, line 1]) for smoothing of the skin and anti-wrinkle of skin, as applied to claims 14 and 15 of the current application.

The claims 1-3, 6, 8, 14-15, 17 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller, D. G. (EP 0180968). *This is a new ground rejection.*

Miller teaches an anti-wrinkle cosmetic composition comprising *human* serum albumin (HAS) protein (see abstract and claims 1 and 7-10) wherein the albumin is derived from expressing a cloned gene for HSA, *i.e.*, recombinant albumin, (see abstract and claims 1, 7 and 8), as applied to claims 1, 3 and 27.

In addition, since Miller teaches a composition comprising the HAS protein (see abstract and claims 1 and 5) which is in a form of a lotion (see page 4, lines 13-17), the Miller teaching is thus applied to claim 2 of the current application.

Miller teaches a composition comprising HAS protein and an aqueous carrier (see the patent claim 1), as applied to the application claim 6.

Miller teaches the HSA protein is dissolved in an aqueous carrier, *i.e.*, 0.5-2 % glycerin solution (see page 3, lines 8-11) wherein the HAS concentration is in the range 5-50% by weight, as applied to claim 8 of the instant application. Because the limitation set forth in the application claim 17, *i.e.*, "1-60 mg/ml", is equal to "0.1g-6 g/100ml", the Miller's teaching is also applicable to claim 17 of the current application.

Further, Miller teaches a method of preparing a skin treating composition which enhances conditioning smoothing the skin and reducing wrinkles by admixing human serum albumin with

aqueous carrier, e.g., glycerine, (see Example 1 at page 4), as applied to claims 14-15 of the instant application.

Response to the rejection under USC 35 102 (b)

The response filed 18 December 2002 discusses the Kligman patent regarding the issue of absorbability of the serum albumin composition of the present claims (i.e., claims 12, 6-12, 14 and 17-18), and infers that because the Kligman patent does not expressly teach the cosmetic composition comprising the serum albumin that can be absorbed into the subject skin, the reference teaching is not applicable to the present claims (see pages 4-5). Note that claims 12, 6-12, 14 and 17-18 are directed to the composition, and the recitation of "the absorbable" to the skin refers to an intended use for the HAS-constituted composition and there is no patentable weight associated with the use of the composition, which chemical structure and biological activity will not be altered due to the use of the composition for conditioning or cleaning skin, for example. Therefore, the applicant's argument is unpersuasive.

Also, the response asserts that Kligman was erroneous in page 1, line 1 wherein the disclosed albumin is not same as albumin set forth in the current application; thus, the albumin protein of the Kligman patent does not disclose or suggest the present composition (see page 5, the last two paragraphs). The applicant's argument is unpersuasive as the following reasons: (i) Kligman does disclose human serum albumin rather than egg albumin (see abstract and claims 1 and 4-5); and (ii) the egg albumen set forth at the patent page 1, line 1, refers to art record rather than the albumin disclosed in the subject matter of the patent.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

Samuel Wei Liu, Ph.D.
March 7, 2003